



FDA Medical Countermeasures Initiative

Protecting National Health and Security

The U.S. Food and Drug Administration (FDA) plays a vital role in [protecting our nation](#) from chemical, biological, radiological, and nuclear (CBRN) agents and emerging infectious disease threats like pandemic influenza.

What is a medical countermeasure?

Medical countermeasures include drugs (e.g., antibiotics to treat anthrax, plague), vaccines (e.g., influenza vaccine), devices (e.g., a test to diagnose a condition or presence of a virus, and equipment like ventilators) that may be needed during a CBRN event or emerging infectious disease threat.

What is FDA's role?

FDA ensures that medical products, including medical countermeasures, are safe, effective and secure. FDA also works closely with [Federal partners](#) and [state and local responders](#) to build and sustain medical countermeasure programs that can meet the needs of Americans during a public health emergency.

What is MCMi?

The Medical Countermeasures Initiative (MCMi) is an FDA program to coordinate medical countermeasure development, preparedness, and response.

When was MCMi launched?

FDA launched MCMi in [August 2010](#) to help strengthen the U.S. capacity to respond quickly and effectively to a public health threat, as mandated by President Obama. MCMi is part of a [large national effort](#) involving HHS, DoD, DHS, CDC, and other Federal agencies.

Who is leading MCMi?

The [Office of Counterterrorism and Emerging Threats](#) (OCET), in the FDA Office of the Chief Scientist, is leading the MCMi. OCET works closely with FDA's medical product centers (CBER, CDER, CDRH) and other offices to meet MCMi goals.

What are the initiative's key goals?

MCMi is protecting national health and security through three main mission components:

- [Public Health and Security Action Teams](#) promote the development and availability of medical countermeasures by establishing clear regulatory pathways
- A robust [medical countermeasure regulatory science program](#) creates the data necessary to support regulatory decision-making
- A collaborative effort to [modernize the legal, regulatory and policy framework](#) establishes effective policies and mechanisms to facilitate timely access to available medical countermeasures

MCMi also helps FDA meet the regulatory challenges posed by new science and technology through collaborative [professional development](#) activities.

Where can I learn more?

Web: www.fda.gov/medicalcountermeasures

Email: AskMCMi@fda.hhs.gov

Twitter: [@FDA_MCMi](https://twitter.com/FDA_MCMi)

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